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Dated: 6/15/05 Signature: Valerie J. Sarosky  
(Valerie J. Sarosky)

Docket No.: SLII-P01-001  
(PATENT)

#5

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:  
Power et al.

Application No.: 10/510876

Confirmation No.: 6247

Filed: October 8, 2004

Art Unit: 1614

For: USE OF OSTEOPROTEGERIN FOR THE  
TREATMENT AND/OR PREVENTION OF  
FIBROTIC DISEASE

Examiner: Not Yet Assigned

INFORMATION DISCLOSURE STATEMENT (IDS)

MS Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Sir:

Pursuant to 37 CFR 1.56, 1.97 and 1.98, the attention of the Patent and Trademark Office is hereby directed to the references listed on the attached PTO/SB/08. It is respectfully requested that the information be expressly considered during the prosecution of this application, and that the references be made of record therein and appear among the "References Cited" on any patent to issue therefrom.

This Information Disclosure Statement is filed before the mailing date of a first Office Action on the merits as far as is known to the undersigned (37 CFR 1.97(b)(3)).

Copies of the U.S. Patent Document references on the PTO/SB/08 are not provided since the USPTO has waived the requirement for supplying copies of U.S. patents for applications filed after June 2003. A copy of each Foreign Patent Document and each Non-Patent Literature Document referenced on the PTO/SB/08 is attached.

Some of the attached references have been cited an International Search Report issued October 17, 2003, during the prosecution of international application no. PCT/EP 03/50080, and a Partial European Search Report issued August 27, 2002 during the prosecution of European Application No. EP 02 10 0364. A copy of the International Search Report and Partial European Search Report are enclosed.

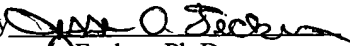
In accordance with 37 CFR 1.97(g), the filing of this Information Disclosure Statement shall not be construed to mean that a search has been made or that no other material information as defined in 37 CFR 1.56(a) exists. In accordance with 37 CFR 1.97(h), the filing of this Information Disclosure statement shall not be construed to be an admission that any patent, publication or other information referred to therein is "prior art" for this invention unless specifically designated as such.

It is submitted that the Information Disclosure Statement is in compliance with 37 CFR 1.98 and the Examiner is respectfully requested to consider the listed references.

The Director is hereby authorized to charge any deficiency in the fees filed, asserted to be filed or which should have been filed herewith (or with any paper hereafter filed in this application by this firm) to our Deposit Account No. 18-1945, under Order No. SLII-P01-001.

Dated: June 15, 2005

Respectfully submitted,

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Substitute for form 1449A/B/PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (Use as many sheets as necessary)				<b>Complete if Known</b>	
				Application Number	10/510876
				Filing Date	October 8, 2004
				First Named Inventor	Christine Power
				Art Unit	1614
				Examiner Name	Not Yet Assigned
Sheet	1	of	2	Attorney Docket Number	SLII-P01-001

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. <sup>1</sup>	Document Number Number-Kind Code <sup>2</sup> (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	A1	4,588,585	5/13/86	Mark et al.	
	A2	4,737,462	4/12/88	Mark et al.	
	A3	4,879,111	11/7/89	Chong	
	A4	4,904,584	2/27/90	Shaw	
	A5	4,959,314	9/25/90	Mark et al.	
	A6	4,965,195	10/23/90	Namen et al.	
	A7	5,017,691	5/21/91	Lee et al.	
	A8	5,116,943	5/26/92	Koths et al.	

FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
		Country Code <sup>3</sup> -Number <sup>4</sup> -Kind Code <sup>5</sup> (if known)				
	B1	WO 92/13095	8/6/92	Synergen, Inc.		
	B2	WO 98/35043	8/13/98	Genetics Institute, Inc.		
	B3	WO 99/53942	10/28/99	Amgen, Inc.		
	B4	WO 02/46225	6/13/02	Applied Research Systems ARS Holding		

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. <sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
	C1	Abraham et al., "Expression and function of surface antigens on scleroderma fibroblasts," Arthritis Rheum, 34:1164-1172 (1991).	
	C2	Bucay et al., "Osteoprotegerin-deficient mice develop early onset osteoporosis and arterial calcification," Genes & Development, 12:1260-1268 (1998).	
	C3	Granot et al., "Halofuginone: an inhibitor of collagen type I synthesis," Biochimica Biophys. Acta 1156:107-112 (1993).	
	C4	Hattori et al., "Bleomycin induced pulmonary fibrosis in fibrinogen null mice," J. Clin. Invest. 106:1341-1350 (2000).	
	C5	Heron et al., "Intracerebral Calcification in Systemic Sclerosis," Stroke, 30(10):2183-2185 (1999).	
	C6	Kostenuik et al., "Osteoprotegerin: A Physiological and Pharmacological Inhibitor of Bone Resorption," Curr. Pharm Des, 7(8):613-635 (2001).	
	C7	Leighton, "Drug Treatment of Scleroderma," Drugs 61(3):419-427 (2001).	
	C8	Malyankar et al., "Osteoprotegerin is an $\alpha\beta_3$ -induced, NF- $\kappa$ B-dependent Survival Factor for Endothelial Cells," Journal of Biological Chem., 275(28):20959-20962 (2000)	

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Sheet	2	of	2		

C9	Martini et al., "Marked and Sustained Improvement Two Years After Autologous Stem Cell Transplantation in a Girl With Systemic Sclerosis," Arthritis Rheum. 42:807-811 (1999).	
C10	Mathiesen et al., "The Clinical Significance of Slightly to Moderately Increased Liver Transaminase Values in Asymptomatic Patients," Scand J Gastroenterol., 34(1):85-91 (1999).	
C11	McGaha et al., "Halofuginone, an Inhibitor of Type-1 Collagen Synthesis and Skin Sclerosis, Blocks Transforming Growth-Factor- $\beta$ -Mediated Smad3 Activation in Fibroblasts," J. Invest Derm., 118:461-470 (2002).	
C12	Min et al., "Osteoprotegerin reverses osteoporosis by inhibiting endosteal osteoclasts and prevents vascular calcification by blocking a process resembling osteoclastogenesis," J. Exp. Med., 192:463-474 (2000).	
C13	Morinaga et al., "Cloning and characterization of the gene encoding human osteoprotegerin/osteoclastogenesis-inhibitory factor," Eur. J. Biochem., 254:685-691 (1998).	
C14	Salant, et al., "Heymann nephritis: Mechanisms of renal injury," Kidney Int. 35:976-984 (1989).	
C15	Shi-wen et al., "Scleroderma lung fibroblasts exhibit elevated and dysregulated type I collagen biosynthesis," Arthritis Rheum, 40:1237-1244 (1997).	
C16	Simonet et al., "Osteoprotegerin: a novel secreted protein involved in the regulation of bone density," Cell, 89:309-319 (1997).	
C17	Smith et al., "Production and function of murine macrophage inflammatory protein-1 $\alpha$ in bleomycin-induced lung injury," J. Immunol., 153:4704-4712 (1994).	
C18	Wigley et al., "Novel therapy in the treatment of scleroderma," Exp. Opin. Invest. Drugs, 10(1):31-48 (2001).	
C19	Wigley et al., "The treatment of scleroderma," Curr. Opin. In Anti-inflam. & Immun. Invest. Drugs, 2:276-292 (2000).	
C20	Yano et al., "Synovial cells from a patient with rheumatoid arthritis produce osteoclastogenesis inhibitory factor/osteoprotegerin: reciprocal regulation of the production by inflammatory cytokines and basic fibroblast growth factor," J. Bone Miner Metab., 19:365-372 (2001).	
C21	Yasuda et al., "Identity of osteoclastogenesis inhibitory factor (OCIF) and osteoprotegerin (OPG): a mechanism by which OPG/OCIF inhibits osteoclastogenesis in vitro," Endocrinology, 139:1329-1337 (1998).	

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